EC-2000-007
IV-D-119

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VIA FEDERAL EXPRESS

February 22, 2002

U.S. Environmental Protection Agency
Enforcement and Compliance Docket and Information Center (2201A)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: DuPont Comments/ Docket Number EC-2000-007

Dear Sir/Madam:

E. I. du Pont de Nemours and Company (DuPont) is pleased to comment on Docket Number EC-2000-007 for the Agency's proposed Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), that was published in 66 Federal Register 46162 (August 31, 2001).

DuPont is a science company, delivering science-based solutions that make a difference in people's lives in food and nutrition; health care; apparel; home and construction; electronics; and transportation. Because many of its operations are regulated by the U.S. EPA, implementation of the CROMERR Rule will directly impact DuPont and its affiliated companies.

DuPont welcomes efforts of the EPA to move in a direction that enables electronic reporting and record-keeping. However, the Proposed Rule imposes an unreasonable financial and resource burden on the regulated community that is not accurately supported in the Proposed Rule, the ICR 2002.02, or the Cross-Media Electronic Reporting and Records Rule - Cost-Benefit Analysis of March 2001.

In addition to the enclosed comments, DuPont has attached for the rulemaking record its comments to ICR No. 2002.02 submitted to OMB on September 27, 2001.

Sincerely,

Kathleen D. Barrowclough

Kathleen D. Barrowclough,
Quality Programs Manager
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Enclosures

SUMMARY

EPA's Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR) 66 Fed. Reg. 46162-46194 (August 31, 2001), is described by EPA as 'allowing' electronic reporting and electronic record-keeping for 40 CFR regulated entities, as prescribed by the Government Paperwork Elimination Act (GPEA)[1].

EPA states, "Under today's proposal, electronic document submission or electronic record-keeping will be totally ***voluntary***..."[2].

EPA's assertion that CROMERRR's record-keeping requirements are "voluntary" is inaccurate and fails to recognize the existing realities of compliance with the Title 40 environmental programs the Agency administers where monitoring cannot be conducted manually. The Agency is aware through its administration of its own programs and through enforcement action that the regulated community currently utilizes nearly universal electronic monitoring and record-keeping practices. The Agency's assertion that the CROMERRR is 'voluntary' is simply not true.

In addition, DuPont concludes that the Agency's CROMERRR proposal for establishing a single stringent criteria for maintaining electronic records in a 'one size fits all' manner[3], whereby all electronic records maintained for the purposes of meeting Title 40 program requirements meet the same criteria (whether for example, an environmental monitoring system, a toxicology data collection system, a policy record, or an indexing tool), is not credible and cannot be supported by the rulemaking record as it currently exists. Rather than removing obstacles to electronic record-keeping as required by the GPEA, the CROMERRR imposes significant cost and compliance burden to the regulated community that, if promulgated, makes compliance with environmental regulations more complicated and difficult.

The rigorous security and control measures applied to all electronic record-keeping systems, the submitter registration process, and electronic signature certification renewals in the proposed rule[4] go beyond what is required to ensure integrity and attributability of electronic records and are not supported by any information in the rulemaking record that suggests the Agency has found that regulated entities produce unreliable records. Imposing additional administrative burdens and additional standards for electronic record generation, retention and reporting versus paper records is simply not supported and is unwarranted. Before it can require such unrealistic and burdensome requirements the Agency must first determine that the regulated community does not currently employ sound business practices for producing high quality data in order to maintain a competitive place in the marketplace.

The rulemaking record is grossly inadequate in documenting widespread fraud or mismanagement by those entities complying with the Agency's programs using electronic record-keeping systems in whole or in part versus regulated entities which utilize only hard paper files.

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[1] The GPEA requires, in part, that EPA, as an Executive agency, provide, (1) for the ***option*** of the electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable. Further, the GPEA requires that the Director of the Office of Management and Budget conduct an ongoing study of the use of electronic signatures on (1) paperwork reduction and electronic commerce; (2) individual privacy; and (3) the security and authenticity of transactions.

[2] Id. at 46162

[3] Id. at 46190.

[4] Id. at 46190-46192.

Review of the *Electronic Signatures in Global and National Commerce Act* (E-Sign Act)[5] reveals two acceptable criteria for an electronic record to satisfy retention requirements for a contract, agreement, or record:

1) it accurately reflects the information set forth in the contract, agreement, or record after it was first generated in its ***final*** form as an electronic record; and
2) it remains accessible, for the period required by such statute, regulation, or rule of law, for later reference, transmission, and printing."

Even a casual reading of the CROMERRR record-keeping requirements demonstrates that the Agency's proposed rule goes beyond the requirements of the E-Sign Act which describes acceptable controls for assuring trustworthy and reliable electronic records and signatures in commerce.

The CROMERRR imposes an unrealistic and unsupported compliance burden on regulated entities[6]. The electronic record-keeping costs included in §2-4 of the *Cost-Benefit Analysis*[7] are deficient and do not include the significant costs associated with:

- Validation of existing record-keeping systems;
- Upgrades to systems as technology changes;
- Archiving of data in a retrievable form for the entire record retention period;
- Migration of data when new systems are implemented; and
- Retrofitting or replacing existing systems to meet CROMERRR record-keeping requirements.

While §3-4 of the *Cost-Benefit Analysis* states that facilities will opt to report electronically only if they deem it cost-effective, the Agency has ignored the fact that states are enacting legislation that require electronic reporting today (e.g., Louisiana) and that other Agencies have already adopted electronic reporting regulations[8].

In addition, EPA asserts in §3-4 of the *Cost-Benefit Analysis*, without any support in the rulemaking record, that facilities which implement electronic reporting have the appropriate information technology infrastructure and will not acquire it solely for electronic reporting under the CROMERRR. While it is true that most, if not all, U.S. companies have implemented some level of electronic support (as, e.g., databases, computers, electronic mail, intranet and internet connection), it is our observation that many such systems currently used in American industry do not meet the CROMERRR's artificially stringent requirements for electronic record-retention systems. And while information technology infrastructure is commonplace for large regulated entities, retrofitting existing systems to meet CROMERRR requirements is costly in both capital expense and resource hours.

DuPont agrees with the assessment in §3-7 of the *Cost-Benefit Analysis* that most reporting facilities will ***not*** have existing automated systems that meet CROMERRR requirements. Additionally, EPA's low-end system costs of approximately $25,000 capital and $15,000 in labor to set up a system, with annual maintenance costs of $17,000 do not begin to capture the costs associated with systems that have the attributes required for CROMERRR electronic record-

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[5] *Electronic Signatures in Global and National Commerce Act*, Public Law 106-229, June 30, 2000, [DOCID: f:pub 1229.106].
[6] See also DuPont Comments to OMB, as Attachment A.
[7] Chaudet, Roy, et al, *Cross-Media Electronic Reporting and Records Rule – Cost-Benefit Analysis,* EP908T2, Logistics Management Institute, March 2001.
[8] 21 CFR Part 11, *Electronic Records; Electronic Signatures; Final Rule;* March 20, 1997, Vol. 62, No. 54, 13430-13467.

keeping standards. Those costs can be closer to $900,000 ($220,000 of which is capital expense) per system for just one archiving system for analytical data.
Since it is acknowledged in the *Cost-Benefit Analysis* that most regulated entities do not have systems that meet CROMERRR requirements; since all the costs associated with developing electronic record-keeping systems have not been considered (as noted above), and; since the pervasive use of automated systems by regulated entities has been underestimated by EPA (as evidenced by EPA's assumption that only 428 facilities per year will make the investment to implement electronic record-keeping, and, therefore, costs associated with this estimated minimal participation are as low as $27,000[9]), DuPont submits that EPA's cost estimates are erroneous and result in an inaccurate and grossly understated cost-benefit analysis. In a similar regulation promulgated by the Food and Drug Administration one White Paper[10] estimated the added cost to the pharmaceutical industry for meeting FDA's 21 CFR Part 11 electronic records and electronic signatures requirements to be in excess of $100 million. CROMERRR compliance for the environmental community will require an unprecedented expenditure far in excess of the unrealistically low number the Agency has suggested in the proposed rule, and is expected to be comparable to the Y2K effort, which DuPont has reported to be ~$310MM.*

DuPont concludes that the appropriate course of action is for EPA to de-couple the record-keeping from the reporting portions of the proposed rule and re-evaluate its approach to electronic record-keeping. Moving forward with electronic reporting when the various state, local, and tribal programs, and regulated entities are prepared can be beneficial to EPA's need to share environmental data, improve the quality of the data, and improve the turnaround time for error corrections. However, DuPont encourages EPA to initiate interactions with the impacted state, local, and tribal programs and other regulated entities so that the Final Rule can be promulgated in a way that meets not only the GPEA mandate for allowing an electronic reporting option (which is already allowable for a great number of regulated programs), but which also takes into consideration existing technology, record retention requirements, the pervasiveness of electronic record-keeping, and the degree of security and control required based on the type of submission and the criticality and impact of the data contained in the electronic records.

DuPont believes there are varying levels of security and system controls for electronic record-keeping systems based on the type data being collected and maintained, the reason for keeping the data, the critical impact on the environment associated with data integrity, cost and quality benefits, and the acceptability of procedural controls in managing the data.

Whatever form the Final Rule takes, DuPont urges EPA to consider providing compliance guidance for regulated entities. Precedence for this request stems from FDA's recognition and issuance of a Compliance Policy Guide[11] to represent the Agency's thinking on what is required to be fully compliant with 21 CFR Part 11. The Agency set forth several criteria that would be used in assessing whether to pursue regulatory actions for non-compliant entities. These criteria included 1) the nature and extent of the Part 11 deviations, 2) the effect on product quality and data integrity, 3) adequacy and timeliness of planned corrective measures, and 4) compliance history of the establishment, especially with respect to data integrity. By acknowledging that regulated entities would not be compliant immediately, but allowing for them to develop plans that would set forth the steps to be taken in order to achieve compliance, the FDA has demonstrated

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[9] Supporting Statement for Information Collection Request Number 2002.02, "Electronic Reporting and Record-keeping – Proposed Rule," p.31.
[10] See, Accenture, *21 CFR Part 11, Achieving Business Benefits,* "Assessing its Impact." This paper is submitted to the rulemaking record as Attachment B of these comments.
[11] Compliance Policy Guide, *Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures* , (CPG 7153.17) U.S. FDA Office of Regulatory Affairs, May 13, 1999.
* DuPont 1999 Annual Report, *Year 2000 Readiness Disclosure,* p. 38

a desire to assist regulated industry in moving toward compliance without penalizing them for their existing state of non-compliance.

Finally, prior to promulgation DuPont urges EPA to undertake a more thorough analysis and evaluation of costs versus benefits, as required by the Administrative Procedures Act and by OMB for implementing the Government Paperwork Elimination Act (GPEA). To the extent that EPA is considering additional stakeholder input, DuPont gladly offers to be a party in any future workgroups.

DISCUSSION

VOLUNTARY ASPECT OF CROMERRR CHALLENGED

1. Current Practices

In §3-5 of the *Cost-Benefit Analysis*[12], EPA acknowledges that many Fortune 1000 entities have automated their environmental monitoring, collection, and data storage. Yet there is no accounting for the significant burden associated with retrofitting these systems to meet CROMERRR electronic reporting and record-keeping requirements. It is not a simple 'connect' as implied in the *Cost-Benefit Analysis.*

Regulated entities **do** keep electronic records for EPA Title 40 programs as part of essential business practices. Halting these business practices is not a viable option; therefore, CROMERRR record-keeping requirements are not "voluntary".

EPA states in CROMERRR §3.2, that electronic reporting requirements may be satisfied if, "EPA has published a notice in the Federal Register announcing that EPA is prepared to receive in electronic form documents required or permitted by the named Part or Subpart of this Title[13]". Likewise, EPA states that electronic record-keeping requirements may be satisfied if, "EPA has published a notice in the Federal Register announcing that EPA is prepared to recognize electronic records under the named Part or Subpart of this Title[14]. This would appear to require that regulated entities already reporting electronically or maintaining electronic records to meet 40 CFR program requirements would be immediately required to change existing practices, thus hampering those entities in their ability to conduct business. DuPont urges EPA to clarify its intentions in this matter and recommends incorporation of compliance guidance for regulated entities to address the Agency's position on existing electronic reporting and electronic record-keeping practices.

EPA indicated in the January 17, 2002, public hearing regarding the electronic record-keeping provisions of CROMERRR that the proposed rule is required in part to establish the acceptability of the use of electronic record-keeping. It is DuPont's belief, however, that this is not the case under the concept of "common practice".....

With respect to electronic reporting, most reporting under CROMERRR is accomplished through state reporting systems. Wherever states promulgate laws requiring electronic

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[12] Chaudet, Roy, et al, *Cross-Media Electronic Reporting and Records Rule – Cost-Benefit Analysis,* EP908T2, Logistics Management Institute, March 2001.
[13] Id., at 46189.
[14] Id., at 46189.

reporting, CROMERRR submitter registration and electronic signature certifications are effectively no longer voluntary.

Guidance from the state of New Jersey regarding its 2001 Emission Statement reporting reveals that NJ has created a personal computer program to help facilities by allowing data to be reported electronically on a diskette rather than on paper. RADIUS software was introduced to the regulated community for the reporting of the 1999 Emission Statement. In 2001, the use of RADIUS was reported to be so successful that 97% of the 2000 Emission Statement reports were submitted electronically and the state of New Jersey encourages continuing this practice. Furthermore, it is DuPont's understanding that the state of New Jersey's compliance strategy includes plans for expanding the electronic reporting process to include an online database.

This example illustrates existing successes in the electronic reporting arena that meet industry and government program needs for data submittal. Has EPA factored in these current state electronic reporting practices and plans?

Some EPA programs have committed considerable resources toward global harmonization. For example, the Office of Pesticide Programs (OPP) has developed relationships with the Canadian Pest Management Regulatory Agency (PMRA) that have resulted in significant program exchanges that enable both governments and applicable regulated entities to leverage reported data in a way that benefits all involved parties.

DuPont encourages EPA to consider these ongoing harmonization efforts, so that potential barriers which might be created by CROMERRR promulgation can be resolved without having a negative impact on international regulatory relationships.

2. Existing Systems

§5-3 of the *Cost-Benefit Analysis* indicates "most organizations probably will choose to report electronically and maintain paper records until technologies evolve that are simultaneously cost effective to implement and sufficiently secure to meet enforcement and archiving requirements."[15]

Regulated entities cannot choose to revert to maintaining paper records. Furthermore, a significant number of existing systems do not meet CROMERRR criteria. For many regulated entities, the cost of meeting compliance as proposed in the short term is incompatible with sustaining a viable business.

One DuPont facility that has a wastewater treatment plant must submit monthly discharge monitoring reports (DMRs). Submittal of DMRs is supported by a laboratory database at the facility, a laboratory database at the contract laboratories which complete most of the required analyses, a software data package that reformats raw laboratory data into the required DMR format, and extensive on-line instrumentation databases for wastewater treatment plant operating conditions. The wastewater treatment plant is operated using a digital control system (DCS), and relies almost exclusively on electronic data transfer.

This example demonstrates that one reporting scenario relies on no less than five different electronic systems to gather and compute compliance information. As proposed, each of these systems is subject to CROMERRR requirements, yet none of the systems currently utilized meets all of the features of the rule. Many of the contract laboratories involved in permit analyses are small operations without the technical resources that would be required

[15] Ibid.

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[15] Ibid.

for retrofitting electronic record-retention systems. These facilities may conduct analyses of data and, as with the regulated entities, use electronic records systems in processing the data.

Another example system is a data logger (Hobo/Stowaway) that logs temperature of soil, water, air, relative humidity, barometric pressure and light intensity. This system cannot be read until it is launched, using the software provided by the manufacturer. While the original data was on the instrument, it is copied to a graph upon downloading. Archiving the original data in human readable form is impossible (Hobos/Stowaways run on lithium batteries that last about two years). It is unclear how CROMERRR would apply to such a system. This is yet another example where the "one size fits all" approach is not realistic.

There are many examples of how electronic systems are used to satisfy regulatory requirements for compliance with each of the 40 CFR programs. Tables I and 2 below provide a high level view of the pervasiveness of information technology to support manufacturing and registration operations. This includes but is not limited to IT support for: process instrumentation, process inventories and raw material consumptions, data summaries, computer modeling and emissions calculations, process and instrumentation diagrams, facility maps and design, operating procedures, personnel monitoring, correspondence, data collection, and accounting systems. These systems are not only inherent to basic plant operating and business functioning, but have also been created for or adapted to regulatory compliance demonstrations (such as DMRs, CERCLA reporting, and air permits).

TABLE I : TYPICAL DUPONT MANUFACTURING SITE

40 CFR Programs	Air emissions inventory Waste water discharges (Part 124) Boiler and Industrial Furnace Regulation Fugitive Monitoring NESHAPS compliance Hazard. waste treatment, storage, disposal
Monitoring Equipment	Distributive Control Systems (DCS) real time monitoring Process Monitoring and Control (PM&C) systems (historian) Spreadsheets (summarizing, calculating, and reporting) Tracking Parameters Programs LIMS System (Lab data) Continuous Emissions Monitoring Systems (CEMS) real time monitoring
Systems on site	8 DCS 6 PM&C 1 LIMS 7 CEMS Numerous spreadsheets Others – LeakDos (Fugitive Monitoring) FEMS (Fugitive Monitoring) WINCEIS Air Emissions Inventory

	STEERS (waste notice of registration & - reporting Plant Ware (Waste Management) Aspen Tech (Waste Management & - Burn planning) TRI WEB (313 reporting) RCM 2000 (CFC accounting)
Databases used to manipulate or store data	6 PM&C 1 LIMS 2 Fugitive Programs 2 State Reports ((STEERS & WINCEIS) 1 Federal Report (TRI WEB) 2 Waste Management 1 CFC Management Several Access® databases Numerous Excel® spreadsheets
Number of DuPont US sites	78
Compliance with proposed rule	Unknown – not likely fully compliant

TABLE II : TYPICAL FIFRA REGISTRATION ENVIRONMENTAL GLP FACILITY

Environmental Controls	Exhaust hoods, refrigerator temperature monitoring, animal room temperature/humidity, growth chambers, light cycle equipment
Data Collection	As many as 30 tox databases and 70 instruments per toxicology facility, biological efficacy databases,
Indexing & Document Management	Numerous electronic systems for indexing, locating, filing records
Modeling	QAR, numerous systems to assist in predictions
Process & Engineering equipment	Chemspeed automated synthesis, Camille, MultiMax, ASI, spray tank mixing, Fieldpro, spray tank cleanout, etc.
Sample Management	Haystack, Agstand, SOS, HotC, HLIS
Ancillary	SOPs, Training Records, Position Descriptions, Guidelines, Policies
Analytical	Characterization analytical systems
Satellite Systems	Field notes

INACCURACIES IN COST TO REGULATED ENTITIES CHALLENGED

3. §2-4 of the *Cost-Benefit Analysis* applies record-keeping costs in FY02 to only TRI reports, DMRs, and other indirect reporting to delegated programs[16]. This approach of applying record-keeping costs to selected reporting programs is flawed in that it does not recognize the pervasive electronic record-keeping practices throughout regulated entities. (See discussion in Section 2). DuPont understands that the American Chemistry Council has made a copy of its record retention guidance document ("The 4R's") available to EPA to demonstrate the breadth of programs that require retention of information. In both the January public hearings and subsequent informal discussions with EPA, industry representatives have shared information regarding the extent to which these records are generated in electronic form.

   §3-8 of the *Cost-Benefit Analysis* summarizes the as-is and to-be costs for electronic record-keeping, and states, "Clearly, it is expensive and if it were implemented widely to meet CROMERRR requirements, the burden would increase significantly. For these reasons, we believe implementing electronic record-keeping will proceed slowly until the cost of technology decreases."[17]

   In addition to the assumption that record-keeping requirements will apply to only a limited number of programs, DuPont contends the per system costs for purchasing or retrofitting existing systems is grossly underestimated. For example, EPA's low-end system costs of approximately $25,000 capital and $15,000 in labor to set up a system, with annual maintenance costs of $17,000 do not begin to capture the costs associated with systems that have the attributes required for CROMERRR electronic record-keeping standards. Those costs can be closer to $900,000 ($220,000 of which is capital expense) per system for just one archiving system for analytical data.

   Please refer to the enclosed DuPont comments on ICR No. 2002.02 submitted to the Office of Management and Budget (Attachment A) for additional data supporting DuPont's position that the financial burden imposed on regulated entities to comply with CROMERRR is grossly understated and is not voluntary in nature.

   Even retrofitting existing systems, since most as-is systems do not meet CROMERRR requirements, is an overlooked financial burden in the *Cost-Benefit Analysis* and *ICR No. 2002.02*. In order to accomplish this monumental task, regulated entities will have to create inventories of existing systems, conduct gap analyses for each, upgrade/replace/retire as necessary, and validate the system against pre-determined user requirements, including CROMERRR electronic records requirements.

   In fact, it has been estimated that the pharmaceutical industry has expended greater than $100 million[18] in meeting FDA's 21 CFR Part 11 requirements for electronic record-keeping and electronic signatures. These expenditures are not the total cost, but rather the cost-to-date. Pharmaceutical companies, for the most part, are not yet compliant and will continue to incur significant costs in the foreseeable future. Some IT professionals believe the effort to determine the status of existing systems with respect to the security features proposed in CROMERRR and the subsequent cost to retrofit or replace these programs so that they would comply will be comparable to the Y2K effort. The cost of Y2K readiness efforts was reported by DuPont to be approximately $310MM.

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[16] Ibid.
[17] Ibid.
[18] See, Accenture, *21 CFR Part 11, Achieving Business Benefits,* "Assessing its Impact." This paper is submitted to the rulemaking record as Attachment B of these comments.

Therefore, the 'significant cost' described in §3-8 of the *Cost-Benefit Analysis* that suggests regulated entities will proceed slowly with implementation of electronic record-keeping, is an order of magnitude larger than that which is estimated in the *Cost-Benefit Analysis*[19] and *ICR No. 2002.02*[20].

CHALLENGE TO 'ONE SIZE FITS ALL' APPROACH FOR ELECTRONIC RECORD-KEEPING

4. EPA has applied one set of record-keeping requirements for all electronic records and electronic documents used to satisfy an EPA-administered federal environmental program under Title 40[21]. Electronic records by virtue of their reason for creation, their uniqueness or reproducibility, their value to the government or to the regulated entity, their proprietary nature, their access features, or their impact on environmental health and safety may require varying degrees of authentication, system security, and other system controls.

   For example, the TSCA[22]/FIFRA[23] GLP community produces safety data for hazardous chemicals and pesticides. The raw data generated to develop risk assessments is critical to the regulated community and relevant agencies. Regulated entities generate and protect that data using available technology and procedural controls, assuring data integrity and reproducibility, as required by GLPs. Not only do the GLPs themselves require that changes in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for the change, shall be dated, and the responsible individual shall be identified[24], an additional requirement is that a statement of compliance or non-compliance accompany data that is submitted with an application for a research or marketing permit[25]. Fulfilling these GLP requirements using this combination of technological and procedural controls has met the needs of regulated entities and EPA regarding the production of reliable, trustworthy data. On the other hand, while records such as training records, position descriptions, SOPs, and tools used to facilitate retrieval of data are maintained in support of those GLP studies, the mechanism for managing those records is not prescribed in the GLPs themselves.

   EPA's intent for CROMERRR applicability to these "other" electronic records is unclear. Current practice may require reduced validation for equipment used to generate non-GLP data, even though it may be used in support of registration, designated as a non-GLP study. Numerous systems and procedures that use computers to generate data for endpoints such as method development, modeling, and range-finding, while non-GLP, provide scientific input for the assessment of a product

   On the other hand, electronic indexing tools enable a regulated entity to provide the EPA with data to support an environmental reporting requirement. However, it would seem more important that EPA receive the data in a timely manner, than it would be for EPA to evaluate the robustness and compliance of the system used to retrieve the data. . Applying stringent

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[19] Chaudet, Roy, et al, *Cross-Media Electronic Reporting and Records Rule – Cost-Benefit Analysis,* EP908T2, Logistics Management Institute, March 2001.
[20] Supporting Statement for Information Collection Request Number 2002.02, "Electronic Reporting and Record-keeping – Proposed Rule."
[21] Id. At 46190
[22] 40 CFR Part 792, *Toxic Substances Control Act (TSCA) Good Laboratory Practice Standards,* September 18, 1989.
[23] 40 CFR Part 160, *Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards*, October 16, 1989.
[24] Ibid., 160.130 (e).
[25] Ibid., 160.12

controls to those systems would impede research and development efforts and add unnecessary cost.

As mentioned earlier, DuPont uses electronic systems to receive, store, transfer, and evaluate data and information for a broad range of business and regulatory needs. Before final promulgation of standards for electronic record-keeping systems, EPA needs to look carefully at a risk analysis of these different types of records to determine the benefit of applying the CROMERRR-proposed security features. This is in alignment with the GPEA and is a critical component of evaluating the appropriate level of administrative and cost burden that this rule may entail. The factors that should be considered as part of this risk analysis include, but are not limited to: ease of access to the data, detectability of data corruption, risks associated with data corruption, any inherent system features that would tend to inhibit or protect against data corruption, and current controls or protections for the equivalent paper records. "Data corruption" should be considered as the intentional or unintentional loss or modification of data.

Requiring all systems to comply with the proposed standards would substantially impact the cost burden on regulated entities, but provide no consequent improvement to the data, compliance or utility to the users of such data. Such artificial requirements are not within the mandate of the GPEA for EPA to relieve the paperwork burden. In fact, the financial burden on regulated entities would increase, but no benefits would be realized.

DuPont recommends that EPA replace the proposed standards for electronic record-keeping with a performance-based standard. The performance standard could require a regulated facility to have adequate procedures and protections in place to ensure that their electronic records are accurate, reliable, etc. This would acknowledge that common industry practices have already addressed most of EPA's concerns with respect to the integrity and accessibility of electronic records, In addition, it would allow each facility or company to determine its own needs depending on the specific systems it uses, rather than EPA trying to predict and regulate the myriad of scenarios that exist.

CLARIFICATION FOR ELECTRONIC RECORD-KEEPING REQUIREMENTS

5. In §3.3 of CROMERRR, EPA defines an electronic record retention system as "any set of apparatus, procedures, software, records or documentation used to retain 'exact electronic copies' of electronic records and documents." §3.100 (a) states, "An electronic record or electronic document will satisfy a record-keeping requirement of an EPA-administered federal environmental program under this Title only if it is generated and maintained by an acceptable electronic record-retention system as specified under this subsection."

   It is unclear to DuPont whether the records requirements apply only to electronic record retention systems that maintain "exact electronic copies,' or whether they apply also to systems that generated the 'original' electronic data.

   EPA has indicated the scope of the record-keeping requirements is sweeping and intended to apply to any records created or maintained for Title 40 programs. This means that monitoring data, data generated or analyzed by contract facilities (both large and small), reporting databases, inventories, tracking spreadsheets, etc., would all be subject to CROMERRR requirements. Small contract laboratories and other regulated entities do not have the information technology infrastructure, nor the information technology expertise required to bring their systems into compliance. This is not to say that DuPont considers the data

generated by these small entities suspect or deficient. Please clarify EPA's position on implementation of CROMERRR for small businesses that cannot comply with the proposed rule. Furthermore, all businesses will be subject to this increased financial burden, and therefore, should be considered in the explicit guidance for implementation. In addition, EPA needs to provide clear guidance on the types of records they will consider to be subject to the retention requirements and whether or not there will be alternative mechanisms for maintaining records with long retention periods.

Compliance monitoring itself is not clearly articulated in CROMERRR. Please describe steps taken to assure an adequate number of sufficiently trained EPA and state resources for conducting this monitoring. FDA has already published several guidance documents to aid both the regulated facilities and the regulators on their CROMERRR-equivalent rule, and several more are in the pipeline for publication. EPA should leverage from the experience of FDA and look for opportunities to streamline the proposed requirements where FDA's experience indicates this is appropriate. Compliance schedules, performance standards, and guidance materials need to be an inherent part of implementation of any electronic record-keeping rule.

ELECTRONIC RECORDS ARCHIVING

6. Maturity of information technology does not currently allow for businesses to comply with CROMERRR for the following reasons:
   - Sheer volume in some areas of data collection and data monitoring make it both technically and financially impossible to either store all data "live" or archive to an alternative media for long term storage.
   - Translation from "machine language", databases, etc., to "human readable form" requires manipulation of original electronic records. Please clarify what portions EPA will require industry to maintain.
   - Renewal of systems to meet future CROMERRR requirements or as part of system life cycle retirement/renewal requires migration of original electronic records. Again, please clarify EPA's expectations on what industry will be required to reproduce in the way of both hardware and software.
   - Media degradation is inevitable. The requirement that industry maintain original electronic records for the life of the product forces media storage upgrade/ replacement over time. Please clarify EPA's definition on "maintaining the original electronic record".
   - One size does not fit all in the area of archival. System types will dictate the requirements needed for maintenance of original electronic records. For example, archival requirements will be different for data collection systems vs. data monitoring systems vs. data manipulation systems. Please clarify EPA's position on producing requirements based on specific data types.
   - As currently written, CROMERRR may necessitate that original electronic records be retained long after the end of the life cycle of the system (hardware and software) that was used for original collection/manipulation. Reconstruction of the original data may not be technologically possible and migration of original electronic records from a legacy system to a replacement system may alter or lose some portions of the original electronic records. Please identify EPA's position on long term storage.

   Due to the financial burden for industry in maintaining electronic systems vs. paper documents, DuPont recommends that EPA re-evaluate the assumption that "paper record" retention periods can be implicitly applied to electronic records.

ELECTRONIC SIGNATURE CERTIFICATION and SUBMITTER REGISTRATION PROCESS

7. As proposed, CROMERRR establishes several new administrative steps in order to submit reports to EPA electronically. As a baseline, current reporting frameworks generally involve the following steps: development of the appropriate data on the appropriate Agency forms, an internal data validation check to ensure that the data is accurate and complete, review of this data with the responsible corporate official (RCO) who will sign the report, RCO signing of the report with the required certification statement, and finally submittal of the report to the state, local or federal agency. The extent of the review of the report contents by the RCOs varies depending on the nature of the report, the facility, and the RCOs themselves. At a minimum, it is expected to include a dialog between the RCO and the primary person responsible for generating the report. The certification language also varies somewhat depending on the program under which the report is being submitted, but is generally some variation of the following:

   > I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all attached documents and, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate and complete. I am aware that there are significant civil and criminal penalties, including the possibility of fine or imprisonment or both, for submitting false, inaccurate or incomplete information.

   This scenario is routinely and easily managed regardless of the methods employed to generate the report to be submitted. It allows for judgement on the part of RCOs to determine the level of review they need to be comfortable affixing their signature. It provides a clear reminder of the consequences of submitting fraudulent information. And finally, it provides a significant level of flexibility with respect to the preparation and submittal of reports as the involvement of the RCO is limited to the end of the process just prior to putting the report in the mail (certified, return receipt requested).

   The proposal under CROMERRR adds several new administrative steps to report preparation and submittal. These steps could become a barrier to the use of electronic reporting, contrary to the requirements of the GPEA. EPA should re-evaluate the registration, certification and submittal issues discussed in the CROMERRR, and look for opportunities to streamline these processes in a way that preserves EPA's need for a named individual while maintaining the reporting flexibility that is inherent to a paper-based submittal.

SUBMITTER REGISTRATION PROCESS

8. As described in the proposed rule [66 FR 46172 – 46176], the registration process for electronic submittals is overly burdensome and is based on several underlying assumptions that are not true for many large facilities. The first paragraph states that "proposed section 3.2000(d) requires that an electronic document receiving system validate only those electronic signatures that are established through a process which registers identified individuals both as system users and as signature holders." There are many instances where the "system user", i.e. person(s) performing data entry, will not be the signature holder. The registration process needs to be flexible enough so that any individual a company determines

needs access to the reporting system can register to use the system. The registrant may ultimately perform a number of functions, depending on the nature of the report – partial data entry, complete report data entry, data entry and signature, or signature only. At a large facility, there can be as many as 6-10 people involved in the generation of a single report, such as the Toxics Release Inventory. Each of these people should ultimately have access to the reporting system in order to enter data and perform a validation step prior to the report being signed and submitted.

In cases where the system user is not the report signer, the registration process as described is unnecessarily complex. EPA should consider an alternative process such as a corporate registration. In a corporate registration, a company can register as many individuals as necessary to complete electronic reporting. The process for registering individuals can be simplified to something as simple as what is currently in use on many existing websites, with a self-selected PIN. The need to add new registrants, as job responsibilities shift, also needs to be as streamlined as possible.

For registrants who will also electronically sign reports, EPA has expressed a need to ensure that the electronic signature carries the same legal authority as a wet-ink signature. EPA has proposed to meet this need via a signature agreement that is submitted as part of the registration for the reporting system. The agreement as described lists eight requirements that the holder of an electronic signature must address. While a one-time certification may not be overly burdensome, some of the elements of the eight requirements described could introduce new complexities or concerns beyond current practices for wet-ink signatures.

1) Agree to protect the signature from use by anyone except me.
   This requirement is intuitively obvious and there are no particular concerns with the concept of having to maintain security of access to the reporting system or to ensure that unauthorized persons cannot sign or submit reports.

2) Understand and agree that I will be held as legally bound...as I would be using my hand-written signature.
   Evolving precedent under the "E-sign" legislation and the changing business landscape lend themselves to the nearly universal understanding that electronic signatures carry the same legal weight as a wet-ink signature. Separate certification to this principle seems redundant and may create a precedent for operating principles for other agencies that receive signed information from industry. EPA's OPP has used a simple certification process for data submitted for FIFRA registrations that incorporates the use of a "Certification with Respect to Data Integrity" form that is completed and submitted with each registration. This system is reported to have worked well for both the Agency and regulated entities. DuPont suggests that EPA review this and the practices of other EPA program offices relative to certification of electronic data.

3) Agree never to delegate the use of my electronic signature.
   If EPA expands the universe of those who can register for the reporting system, concerns around this restriction may be somewhat tempered. However, there are occasional business realities where the RCO required to sign a report is not available at the time of submittal. While this situation may be rare, there is often a trusted assistant who has the authority to sign documents in the RCO's stead with the explicit permission of the RCO. DuPont requests clarification around how the delegation of authority might play out in CROMERRR's electronic signature certification and submitter registration processes. DuPont believes that as long as the RCO takes responsibility for the document to which his or her signature has been affixed, the prohibition on delegation should be lifted.

4) Understand that whenever I electronically sign and submit an electronic document...a copy of my submission as received will be made available to me.

5) Agree to review the acknowledgements and copies of documents I electronically sign and submit.
Item 5 is potentially problematic in the context of earlier comments regarding the fact that the person who signs the report is generally not the person who has prepared the report. For this reason, the signer may not be qualified to review any copies of documents he or she has submitted to ensure the data has not been corrupted in the process of transmittal. This requirement should be deleted. As an alternative, see comments to item 2 above for "Certification with Respect to Data Integrity". EPA should allow the opportunity for review of data by the RCO who signed the report, but the RCO should not be required to certify that he or she has done so. The acknowledgement and/or copies of the submitted information need to be made available to registrants other than or in addition to the signer of the report to ensure that the information sent is what was received.

6) Agree to report within twenty-four hours of discovery, any evidence of the loss, theft, or other compromise of any component of my electronic signature.

7) Agree to report within twenty-four hours of discovery, any evidence of discrepancy between an electronic document I have signed and submitted and what has been received from me.
EPA will need to provide guidance on the mechanism for transmitting and documenting these reports. E-mail notification is the preferred mechanism. EPA also may need to address a reasonable time to make the discovery described in Item 7 (i.e. one week, one month?).

8) Agree to notify if I cease to represent...as signatory of that organization's electronic submissions...as soon as this change in relationship occurs and to sign a surrender certification at that time.
DuPont has several concerns with this requirement. First, "as soon as" is not defined – is this one business day, one week, etc.? Second, this requirement seems unnecessary as the new RCO will be required to register (if not already registered) and submit what will hopefully be a streamlined one-time certification. To require notification to EPA of changes in responsibilities of RCOs goes far beyond current administrative requirements for submitting paper reports. The other elements of the certification seem to provide adequate protection that the signer of a report is authorized to do so, and corporate registrations would require that companies maintain current records of those who need to be registered to use the reporting system and have the authority to sign reports.

As indicated above, DuPont does not believe that a periodic renewal of this certification is required or adds any value to the implementation of electronic reporting. A one-time certification provides assurance to EPA that the individual(s) who are affixing an electronic signature to a report understand their responsibilities with respect to the use of an electronic signature. We reiterate our request that EPA consider a streamlined approach to this certification more consistent with the OPP's approach for certifications of data integrity when new FIFRA materials are registered. This certification could be managed as part of a corporate registration to submit electronic reports.

EPA is also asking for comment on a possible alternative to the requirements discussed above by codifying a requirement that signature holders provide information upon request

regarding "'certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.'" [66 FR 46174, col.3] This is entirely preferable to the overly prescriptive requirements described in the preceding paragraphs.

DATA VALIDATION

9. EPA has proposed that the reporting system only accept reports that have been signed after the submitter has scrolled through all the data, that each screen displays a certification statement, and that the submitter has seen a warning that reinforces that he or she is signing a report in accordance with the previously submitted certification and signature agreement. This approach appears to be redundant and neglects to acknowledge common business practices with respect to report signing. Screen-by-screen certification is the equivalent of having every page of a report signed by the RCO. This is not common practice, and could become extraordinarily burdensome for large reports or permit applications. In addition, if EPA is going to go through the steps to require signature agreements, the need to provide screen-by-screen certification and a final warning is redundant.

   DuPont recommends that EPA consider eliminating the signature agreement and retain language in the final report submittal step that includes a statement to the effect that "the submitter fully understands that by activating the [electronic] signature, he or she is taking a step with the same legal implications as signing and sending a report on paper." [66 FR 46175] If EPA maintains the signature agreement requirement, there is no need to codify additional requirements that become part of document submittals.

   There is an additional concern that is raised within the context of EPA referring to the "signer" as the "submitter". There are many cases where the signer of the report will ultimately not be the person actually submitting (i.e. mailing) the report. Administrative flexibility often requires facilities to work within the scheduling allowance of the RCO, so that there may be a small amount of report preparation that must be completed after the RCO has signed the submittal sheet of the report. EPA is eliminating this necessary business flexibility by making the signing of an electronic report occur simultaneously with the submittal of the final document. EPA should rethink this particular step in the submittal process to allow for necessary business flexibility.

   Finally, EPA needs to determine the most feasible way that actual data validation can be executed by those who prepared the report, rather than by the person who signed the report. The requirements associated with the actual affixing of an electronic signature state that a copy of the submitted report will be sent to the person who signed/submitted the report. DuPont recommends that an individual other than the signer can be the submitter, and that the submitter receives an acknowledgement and copy of the report that can be validated. This is consistent with current practices involving paper reports and is the most efficient way of ensuring that adequate report validation is completed.

   While DuPont appreciates the underlying rationale that EPA has used to establish the requirements associated with electronic reporting, we believe that there are many practical concerns that have not been addressed and may make the process overly burdensome or difficult to implement in a real business context. In summary, these concerns include the following:

   - The need to register numerous individuals across the company, many of whom will not be signing reports;

- The need to minimize the administrative burden associated with registration to ensure normal workflow and recognize business flexibility needs;
- The redundancy that appears to be present in the registration, signature agreement, and report certification processes;
- The need to maintain business flexibility with respect to obtaining timely signatures from the responsible corporate official (RCO);
- The increase in administrative burden that appears to be built into the need to certify individual screens in a report submittal vs. current practices (not signing every page of report);
- Managing issues associated with the signer/RCO not being the person who ultimately submits the report in current practice;
- The proper procedures for ensuring timely report validation by the appropriate personnel (report preparer(s) vs. report signer); and finally
- EPA has presented a "one size fits all" approach to electronic reporting, which may not be appropriate for all types of reports. Requirements for "controllable" elements such as signatures and validation should be flexible enough to accommodate different reporting needs, or should be transparent enough so as not to present a barrier in any reporting scenario.

CDX – ELECTRONIC REPORTING/EXCHANGE OF DATA

10. DuPont requests that EPA consider the following issues related to CDX and their impact on industry:

    - Identify a process for enabling state agencies to share standards for report CDX formats. A company may be required to report the same data to multiple states. Standard CDX report formats will reduce the burden on industry to maintain multiple CDX reporting systems.
    - Allowance for industry to implement systems that establish a connection with state document receiving systems. Most industry IT systems that are now used for state reporting would require enhancement, upgrade, and complete validation per the proposed electronic record keeping rule at substantial cost and resource commitment from industry.
    - Some companies maintain corporately controlled intra/internet access (e.g., firewalls). The technology required to enable CDX transmissions may require corporate or at minimum local technology infrastructure upgrades. Again at significant cost to industry. Additionally, CDX access through a corporate firewall may not be technologically possible and may require the design, purchase and implementation of a specialized solution just for CDX reporting purposes.
    - Current vendor applications may not technically support connectivity or CDX capability and may require significant commitment from both vendors and industry to complete. This could require both resource burdens and capital investments.

In summary, DuPont envisions a significant financial burden for regulated entities in implementing CDX. Please describe the steps taken to assure control of minimum standards for CDX among state agencies.

DuPont requests that EPA reconsider the specific administrative steps proposed in the CROMERRR, and that EPA seek additional input from regulated facilities, both large and small, to identify solutions that are implementable in any business context before promulgating this rule.

White paper

21 CFR Part 11

Achieving business benefits

accenture

Pharmaceuticals & Medical Products

Attachment B

DuPont Comments CROMERRR/66 Fed. Reg. 46162 (August 31, 2001).
Docket No. EC-2000-007

The pharmaceutical and medical products industries are increasingly moving into the digital world by becoming more dependent on information technologies. As part of this shift in the industry business model, companies are focused on ensuring both data security and integrity. Regulations such as Part 11 of Title 21 of the Code of Federal Regulations, the Food and Drug Administration's final rule on electronic records and electronic signatures, reflect this changing business landscape by defining the controls required to utilize such technologies for regulated applications. While this paper focuses on 21 CFR Part 11, other United States Federal regulations, currently being introduced, establish similar requirements that may, in fact, broaden the scope of these requirements.

Part 11 has had and will continue to have a large impact on pharmaceutical and medical products companies. This rule affects many areas within an organization and has high cost implications requiring clarification of roles, remediation of computer systems and training. Despite being an American regulation, it can also have an impact on facilities and companies outside the United States.

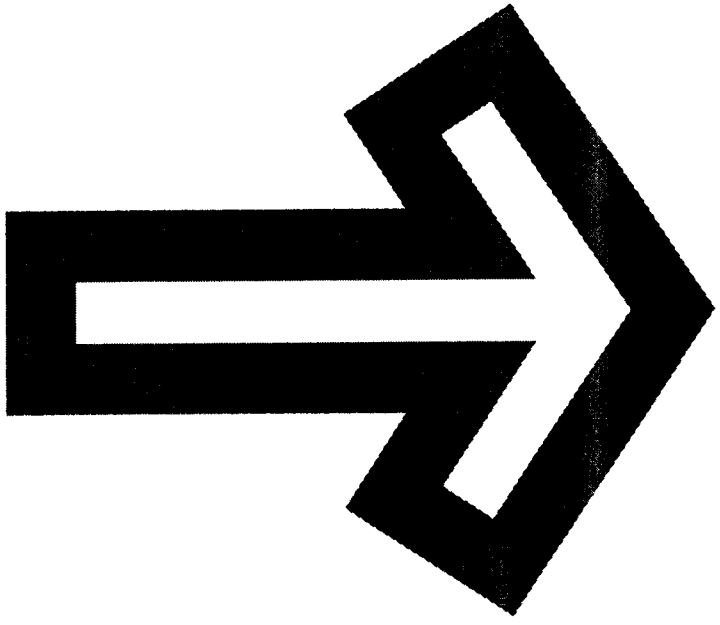
Achieving Part 11 compliance has not been easy. This is due, in part, to the evolving interpretation of the rule. Other challenges include a lack of funding and time, partly due to a prior focus on Y2k remediation, the rapid evolution of electronic record/electronic signature technologies and the need for resources with the appropriate skills.

While the premise that the Part 11 regulation requires costly courses of action is largely undisputed, the business benefits associated with the move to electronic records and electronic signatures often go unmentioned. That is, companies that utilize electronic records and/or electronic signatures and, therefore, must comply with Part 11, will gain increased data integrity, quality and security, all while implementing more

Key actions industry can take to manage their approach to compliance with Part 11 are:

- Incorporate Part 11 requirements into the corporate-wide quality program with senior executive support and leadership
- Manage the cost and complexities of regulatory compliance through early and complete compliance/remediation planning, prioritization and implementation
- Architect an enterprise-wide game plan that addresses people, processes and technology from a strategic perspective
- Be pragmatic in staging the implementation by targeting the "basics" first and focusing on the rule's intent.

After a brief introduction to the rule, this paper discusses Accenture's views on the current impact and challenges of attaining compliance with Part 11. It also offers some insights and considerations on viewing compliance with the regulation in light of the business benefits associated with the

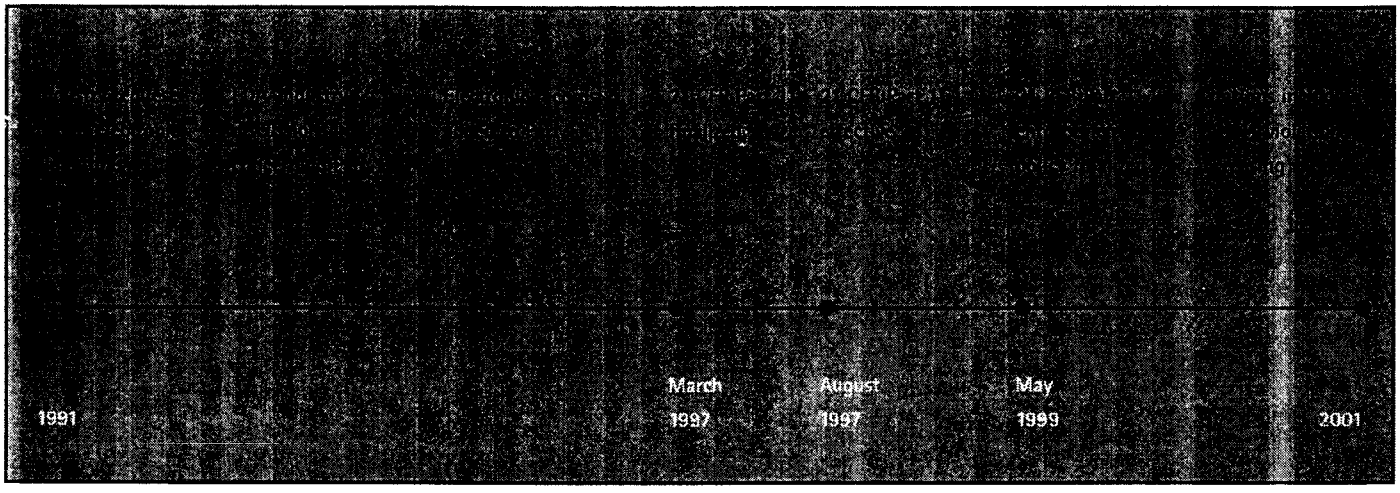


Setting the stage

Unlike most government regulations, Part 11 of Title 21 of the Code of Federal Regulations, the rule on electronic records and electronic signatures, was developed in response to industry's request to accommodate new technologies.

Unlike most government regulations, Part 11 of Title 21 of the Code of Federal Regulations (CFR), the rule on electronic records and electronic signatures, was developed in response to industry's request to accommodate new technologies (i.e., electronic signatures). It was written with significant industry input over a period of six years. The final rule was published by the Food and Drug Administration (FDA) in March 1997 and took effect in August 1997. Figure 01 identifies some key milestones in the development and enforcement of Part 11.

Figure 01
Highlights of the 21 CFR Part 11 timeline



The regulated industries are increasing utilization of electronic record and electronic signature capabilities, which add value to their core business by enabling:

- Greater efficiencies
- Improved accuracy in capturing data
- Easier access to information
- More rigorous quality controls
- Tighter security for proprietary data

Via the Part 11 rule, the FDA has defined the regulatory requirements that must be met for FDA acceptance of electronic records and/or electronic signatures in place of their paper representation. The price of the above business benefits associated with the use of electronic records and/or electronic signatures, then, is an increase in the cost and complexity of implementation due to requirements of Part 11 compliance. However, there are ways to manage this additional cost and complexity while still ensuring regulatory compliance.

This paper discusses several aspects of Part 11, namely, some key information about the rule itself, its significance to industry, the associated challenges and considerations for developing and managing compliance strategies.

Introducing the rule

21 CFR Part 11 outlines the procedural and technical requirements necessary to implement computer systems utilizing electronic records and/or electronic signatures.

21 CFR Part 11 outlines the procedural and technical requirements necessary to implement computer systems utilizing electronic records and/or electronic signatures. These controls include, but are not limited to, user authentication, system access/security, audit trails and record retention. In addition, the rule requires that all systems subject to Part 11 be validated via Computer Systems Validation (CSV)-compliant procedures.

Key definitions associated with Part 11

The FDA defines an electronic record as "any combination of text, graphics, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system".

An electronic signature is defined within the rule as "a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature."

A closed system is one in which "system access is controlled by persons who are responsible for the content of electronic records that are on the system."

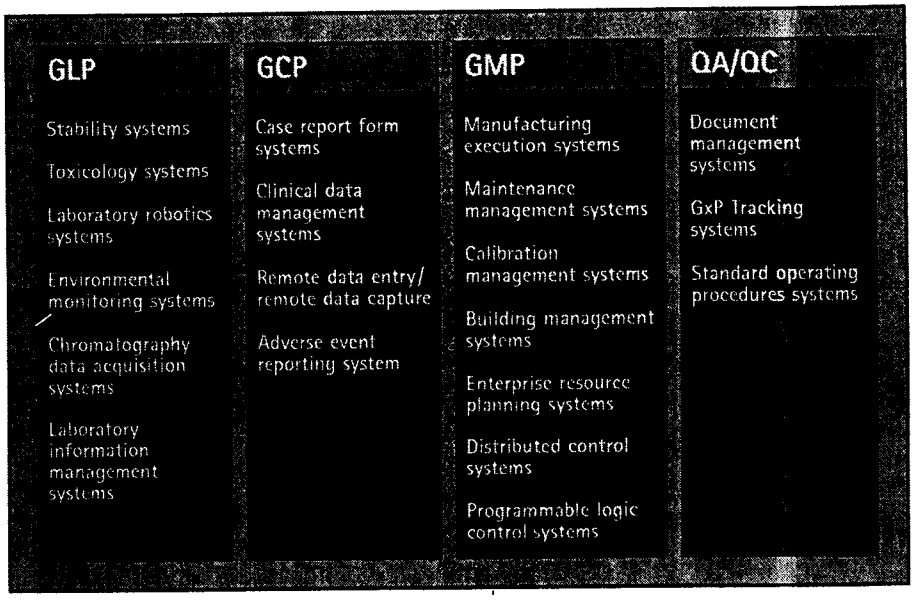
An open system exists when "system access is not controlled by persons who are responsible for the content of electronic records that are on the system." For example, use of Electronic Data Interchange (EDI), the Internet and dial-up via modem (not through a Virtual Private Network) would be considered open.

For electronic records, the rule identifies additional required controls for open versus closed systems. Specific electronic signature requirements identify controls for biometric (i.e., based on individual physical characteristics such as a fingerprint or retina) versus non-biometric signature manifestations.

Part 11 applies to data that directly affects product, quality or distribution. It also applies to data about people and/or processes that directly affect product, quality or distribution. Electronic records created **after** the rule was effective (August 20, 1997) are clearly under the scope of the rule. However, Part 11 also applies to electronic records that were created **before** August 20, 1997 if they have been modified, maintained, archived, retrieved or distributed via a computer system since that date. Therefore, new as well as legacy systems, which affect electronic records subject to the rule, need to be in compliance.

The intent of the regulation is to ensure that electronic records and electronic signatures are "trustworthy, reliable and generally equivalent to paper records and handwritten signatures" (21 CFR Part 11).

Figure 02
Examples of systems subject to Part 11



While the regulation applies to all FDA program areas, use of electronic records and/or electronic signatures is not mandated. Rather, Part 11 applies when a record or signature, required by a predicate rule (e.g., Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP)), is created, maintained, archived, retrieved and/or distributed electronically. In other words, Part 11 controls are required above and beyond the existing regulations; they do not replace them. Figure 02 provides examples of GLP, GCP, GMP and Quality Assurance (QA)/Quality Control (QC) systems for which Part 11 applies.

Not all systems that utilize electronic records and/or electronic signatures implemented by companies that fall under the governance of the FDA need to comply with 21 CFR Part 11. For example, electronic batch data and training records would be within the scope of this rule, as they are required by predicate rules, but electronic financial records would not be. However, other government agencies (e.g., Securities and Exchange Commission (SEC)) are in the process of issuing similar regulations, which may mandate similar requirements for electronic records/signatures not covered by Part 11.

Assessing its impact

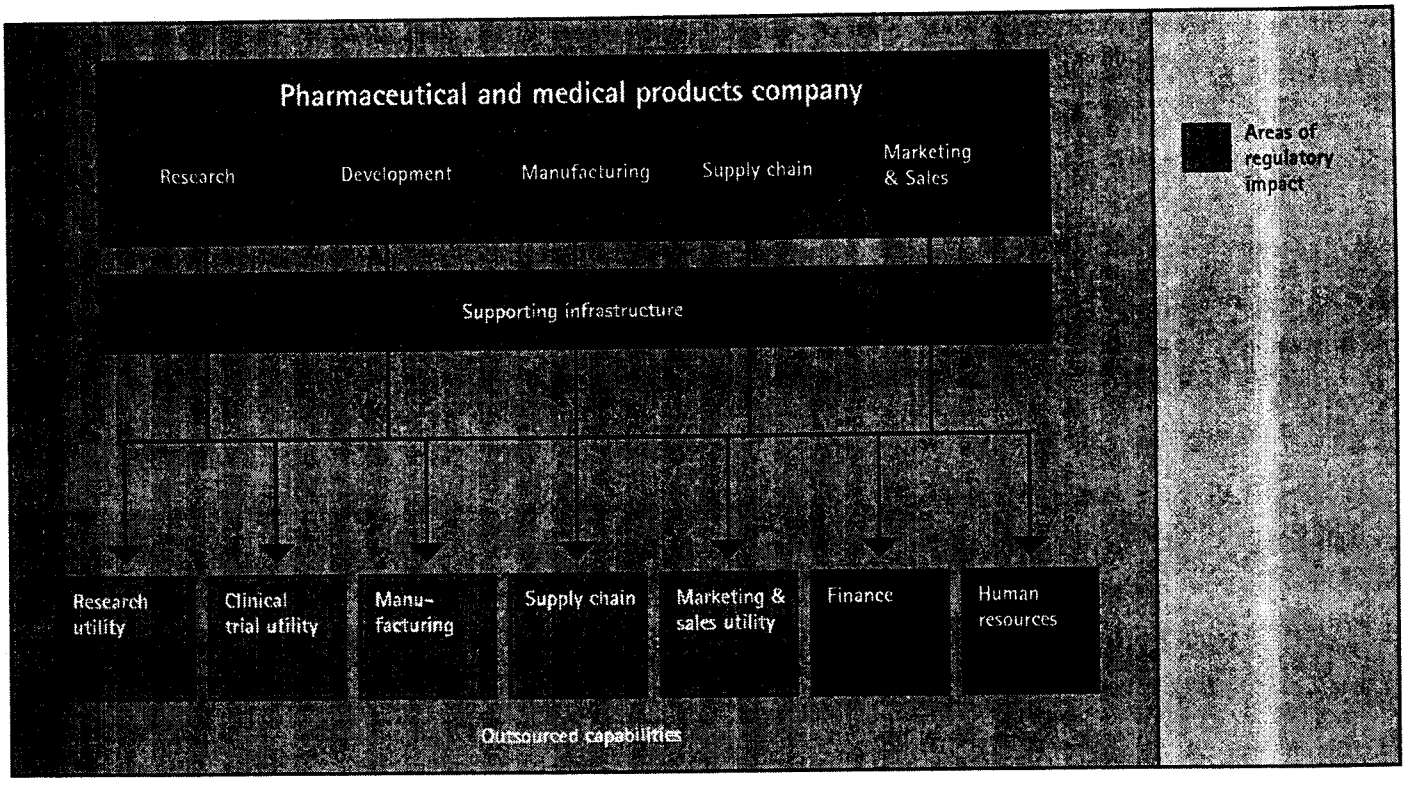
The pharmaceutical and medical device industries have historically been dependent on manual, paper-intensive procedures to ensure the quality and safety of products.

The pharmaceutical and medical device industries have historically been dependent on manual, paper-intensive procedures to ensure the quality and safety of products. As demand and cost pressures increase and as the "bar" for quality and safety is raised, it becomes increasingly difficult to rely on manual processes. The industry is, therefore, quickly becoming more dependent on computer systems to ensure the quality and safety of pharmaceutical products and medical devices.

This increase in computer system usage will increase the impact felt by Part 11, as all systems employed to ensure the quality and safety of pharmaceutical and medical products will be subject to Part 11 compliance. In addition, we are starting to see some ramifications of non-compliance with 21 CFR Part 11.

This section identifies some key reasons why Part 11 is and has been a topic of significance to the pharmaceutical and medical device industry.

Figure 03
"Virtual value chain" and areas of regulatory impact

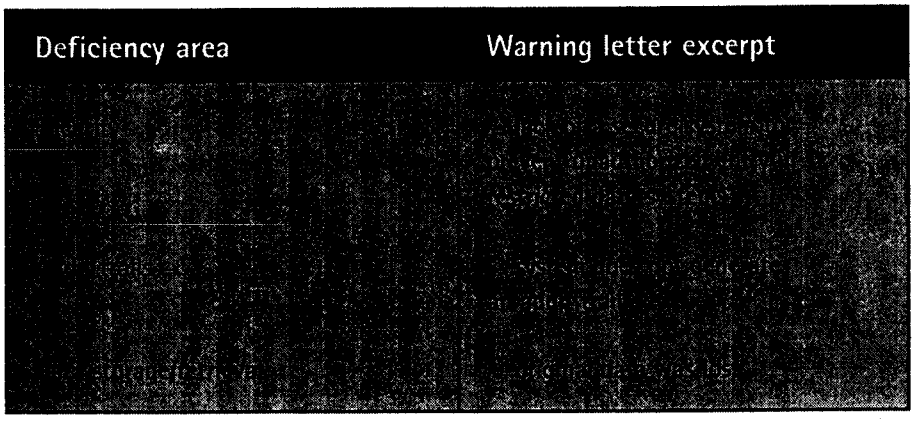


Broad scope

One reason that Part 11 has a notable impact on pharmaceutical and medical device companies is that this regulation has such a broad scope.

- Part 11 applies to both newly installed and existing systems. Legacy systems that are used to modify, maintain, archive, retrieve or distribute pertinent electronic records were not "grandfathered" by the rule.
- While not literally as broad as Y2k in the number and type of systems affected, the reach of "regulated records" spans the entire value chain and several support functions such as Quality and Information Technology. It also affects procedures and personnel responsible for these records.
- Lastly, companies are developing more alliances and partnering relationships with many different stakeholders. These companies are likely to employ computer systems to efficiently exchange information with their partners. In these cases, the scope of Part 11 extends across company borders into the "virtual value chain", depicted in Figure 03.

Table 01
Warning letter excerpts identifying Part 11 compliance deficiencies



Large investment of time and money

Depending on the extent of legacy systems deployed, the impact of Part 11 could be greater than the Y2k remediation effort. Part 11 establishes new requirements for legacy systems that were previously not explicitly defined as essential for regulatory compliance.

In a recent survey conducted by Accenture concerning leading companies' approaches to Part 11 compliance, respondents place the total cost to become compliant with 21 CFR Part 11 at about $100+ million, with additional time and money slated for maintenance.

Given the necessity to invest such a large amount of resources, both initially and on an ongoing basis, this regulation has a greater direct financial impact than many other regulations for pharmaceutical and medical device companies.

Risk of non-compliance citations

As with all federally mandated regulations, companies not in compliance may receive a Form 483, warning letter or more severe reprimand such as delaying a new product launch or closing facilities, depending on the nature and extent of the infraction.

Given the significant effort required to attain Part 11 compliance as well as the burden of Y2k remediation programs, the FDA gave industry an unofficial "grace period" to become compliant with Part 11 **after** the ruling went into effect. The FDA deems that there has been enough time for companies to become compliant with the regulation. The grace period is over; the FDA is auditing for Part 11 compliance as part of routine audits and they are starting to cite Part 11 non-compliance.
A sample of warning letters, listed in Table 01, identified Part 11 compliance deficiencies in security, audit trails and data storage/retrieval.

Global reach

21 CFR Part 11, although authored by an American regulatory agency, can also have an impact on organizations outside the United States. Facilities or companies not physically located or based in the United States are not necessarily exempt from 21 CFR Part 11 due to their physical location. As long as there is a direct impact on product, quality or distribution for a product marketed or sold in the U.S., the regulation applies to non-U.S. based organizations or facilities.

Recognizing the challenges

Moving to electronic records and electronic signatures creates tremendous value for pharmaceutical and medical products companies in terms of speed, efficiency and accuracy of information.

Moving to electronic records and electronic signatures creates tremendous value for pharmaceutical and medical products companies in terms of speed, efficiency and accuracy of information. However, assuring compliance with 21 CFR Part 11 is similar to meeting CSV requirements in that it adds considerable complexity and cost to systems development and maintenance. Furthermore, its application to legacy systems and electronic records poses a potentially significant remediation cost.

Many companies are still grappling with the regulation as evidenced by recent FDA citations referencing Part 11.

Lack of urgency to attain compliance

Although Part 11 was finalized several years ago, there has been and still is a relatively low sense of urgency around 21 CFR Part 11 compliance due to one or more of the following:

- Little understanding of the impact of the regulation
- Perception of there (still) being a "grace period"
- Low visibility of FDA warnings/ observations
- View of 21 CFR Part 11 as lower risk compared to major GxP issues
- Perception that "As long as you have a plan – you are OK"

This lack of urgency may increase remediation costs down the road. In

A moving compliance target

With the demand for new technology continuing to increase, the task of becoming, and staying, compliant is a growing challenge. Compliance is not a one-time event. Significant effort is associated with remaining compliant, which requires people and knowledge. Many organizations today are not staffed, organized or trained to handle the "extra" workload.

In addition, while comprehension of 21 CFR Part 11 is much better now than when it was first finalized, interpretations vary widely by pharmaceutical and medical device companies, software companies, hardware companies and others. This is due, in part, to the nature of government regulations. As with many other regulations, Part 11 is not, and could not be, written in a prescriptive manner. The intent of the rule is prescribed while individual companies must determine the specific methods for becoming compliant.

The FDA is not trying to "trap" industry, but rather it leaves the door open for companies to implement procedures and technologies best suited to their own organizations rather than having to "force-fit" federally mandated procedures and technologies. This, however, adds to the time and effort required by companies to first understand the regulation and then to determine an appropriate course of action for becoming compliant.

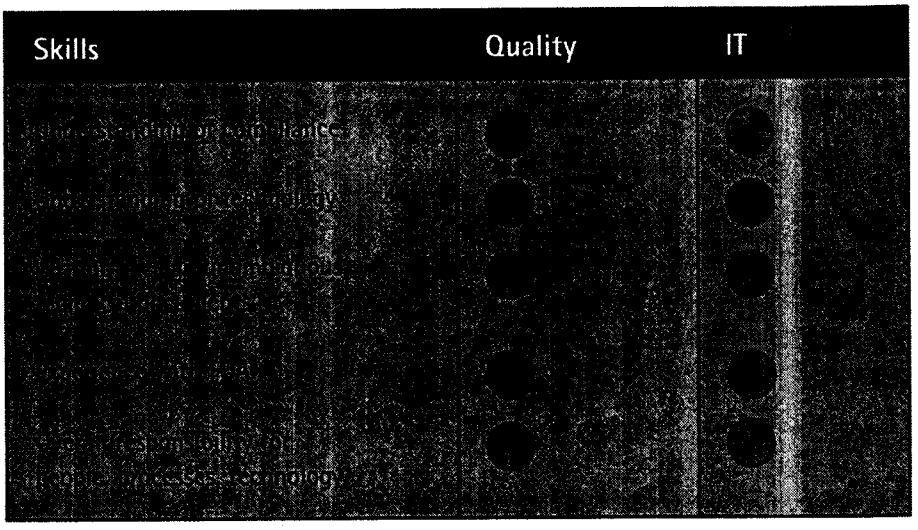
Lack of clear accountability

Since 21 CFR Part 11 impacts many functional areas within an organization, there is typically not one single point of ownership and accountability. As a result:

- There are many different compliance/ remediation efforts going on within an organization which are not coordinated and consistent
- The Part 11 program does not have a comprehensive scope, i.e., it does not include people, processes **and** technology.

Both of these scenarios create a huge potential for compliance risk as well as an additional (unnecessary) investment of time and cost for companies in the form of redundant efforts.

Table 02
Skills required and available by department



Those individuals responsible for Part 11 compliance typically do not have the full complement of skills and experience required to ensure compliance. Quality and Information Technology (IT) professionals tend to be the most involved with planning and executing Part 11 compliance and/or remediation programs. However, as illustrated in Table 02, neither group alone has all the skills required to achieve compliance. Furthermore, their influence and empowerment to direct change across the enterprise are severely constrained.

Compliance of packaged applications

Pharmaceutical and medical device companies increasingly rely on commercially available computer systems. This includes software specific to the industry, such as remote clinical trial packages, as well as enterprise-wide, cross-industry applications such as Enterprise Resource Planning (ERP) systems.

Software companies that specifically serve the pharmaceutical and medical device industry are now beginning to focus on compliance with 21 CFR Part 11. Many claim that they provide software that is both validated and compliant.

This raises two issues:
- Software companies may not have the skills and experience with regard to compliance with federal regulations
- Software itself cannot be compliant "out of the box" as people, processes and CSV procedures are also part of achieving compliance.

Compliance accountability remains with the organization implementing the software. This includes evaluating commercial software claims regarding Part 11 compliance via a thorough audit followed by compliant implementation procedures.

A trend in technology applications is to expand functionality with more integrated activities. While this trend has its benefits, the extensive integration across the value chain further complicates the ramifications of Part 11. For example, many large systems, such as ERP packages, create and maintain some records that fall under 21 CFR Part 11 and others that do not, creating a gray area for determining both compliance and validation strategies.

Lastly, vendors who produce software across industries may not be influenced to update their packages for Part 11 compliance, as it is not required for all of their customers. Extra effort is required on the part of the pharmaceutical or medical products company to supplement these packages to ensure regulatory compliance.

Lack of relevant experience in the FDA field force

With regard to technical savvy, industry is usually at least one step ahead of the FDA in depth of skills. Generally, FDA inspectors do not yet have the skills to perform detailed Part 11 reviews, as they do in other areas. This might be creating a perception that it is easy to pass a review of 21 CFR Part 11. However, the FDA does not have to be on the cutting edge of technology to understand how it works and how it impacts product and quality.

Recognizing the industry's increased dependency on computers and computer systems, the FDA continues to invest in their development of computer systems expertise. They are also increasing their focus on CSV and 21 CFR Part 11 as part of their routine audits, all of which compounds the pressure on industry to "get it right".

Developing a compliance approach

With all of these challenges simultaneously converging on pharmaceutical and medical device companies, it is time to take a new look at compliance, specifically with regard to 21 CFR Part 11.

Further deployment of electronic records and electronic signatures promotes efficiencies and provides strategic value. In addition, more companies are recognizing the value of increased emphasis on quality (e.g., six sigma programs). They are also placing more importance on data security to protect their information assets and prevent fraud. Meeting Part 11 compliance requirements, then, is central to achieving these business benefits.

This section summarizes four key actions for achieving and maintaining compliance with Part 11 while managing its costs, complexities and risks.

Leverage the corporate-wide quality program

The explosive growth in the application of digital technologies to improve efficiency and access to information cannot be ignored. These new capabilities are enabling faster and more extensive interchanges across the organization, and with alliance partners, customers, regulators and many other stakeholders needing access to distributed information. However, the move to a more comprehensive electronic environment poses additional legal and security risks that must be addressed to protect these highly proprietary information assets. These initiatives and issues are collectivelv

Compliance with 21 CFR Part 11 must be viewed in the broader context of this emerging business landscape. The regulatory intent of 21 CFR Part 11 is to ensure data integrity and quality as well as to prevent fraud. Data about a product, whether in development or on the market, is a business asset and, as such, should be kept secure and reliable. Thus, Part 11 provides the appropriate guidelines for protecting this valuable asset.

Many companies have initiated a corporate-wide quality program following the widely acclaimed success of six-sigma programs within General Electric Corporation and other high performing companies. Part 11 compliance should be addressed as part of this corporate-wide quality program, led by empowered senior executive(s).

Addressing Part 11 compliance in this way will raise the awareness of similar requirements from other emerging regulations. For example, the SEC recently published its rule for electronic signatures, fashioned after 21 CFR Part 11. The regulations for the Health Insurance Portability and Accountability Act (HIPAA) also have requirements similar to those in Part 11.

In addition, viewing Part 11 compliance at a senior, corporate level has the benefit of addressing the legal and business risks stemming from the emerging distributed electronic environment. Accenture's recent survey of leading companies' approaches to implementing Part 11 requirements indicated that responsibility typically resides with the IT and QA functions. However, these groups do not have the breadth of visibility into business risks nor other regulations to drive a comprehensive program addressing data integrity and security issues.

Manage the cost and complexity

There is no denying the fact that Part 11 requirements will increase the time and budget required to implement regulated information systems. However, if done right, achieving compliance will eliminate business risk, improve information quality and achieve greater consistency and efficiencies in key business processes.

The Part 11 plan should prioritize the remediation activity, addressing procedural enhancements and individual remediation efforts in the context of the longer term technology plan and architecture. For example, Part 11 programs should begin by defining key "information policies", such as who has authority to author and/or change information, who has access to information, record retention policies, etc. These policies will provide the framework for achieving compliance, through administrative means in the near term or via innovative technology solutions longer term.

There is a striking parallel between compliance with Part 11, as described above, and CSV compliance. CSV has often been viewed as a "necessary evil" which adds incremental time and cost to tightly budgeted development projects. However, companies are coming to realize the value in applying a life cycle methodology to the development, implementation and maintenance of computer systems.

At a basic level, CSV requirements mandate the generation of a paper trail which documents that the life cycle methodology has been followed. If the appropriate procedures are in place and they are followed correctly, this approach adds approximately 15% to the overall development effort, but, if ignored, could add upwards of 50%.

While Part 11 compliance is a "cost of doing business", it also is an enabler of improved business processes that address quality and efficiency through technology and reduce business risk. As with CSV, addressing Part 11 later can result in higher costs, both monetarily and in terms of severity of regulatory citations. The recent Accenture Part 11 compliance survey revealed that, in one case, a company cited for Part 11 non-compliance spent in excess of $1 million for remediation and validation for a single system.

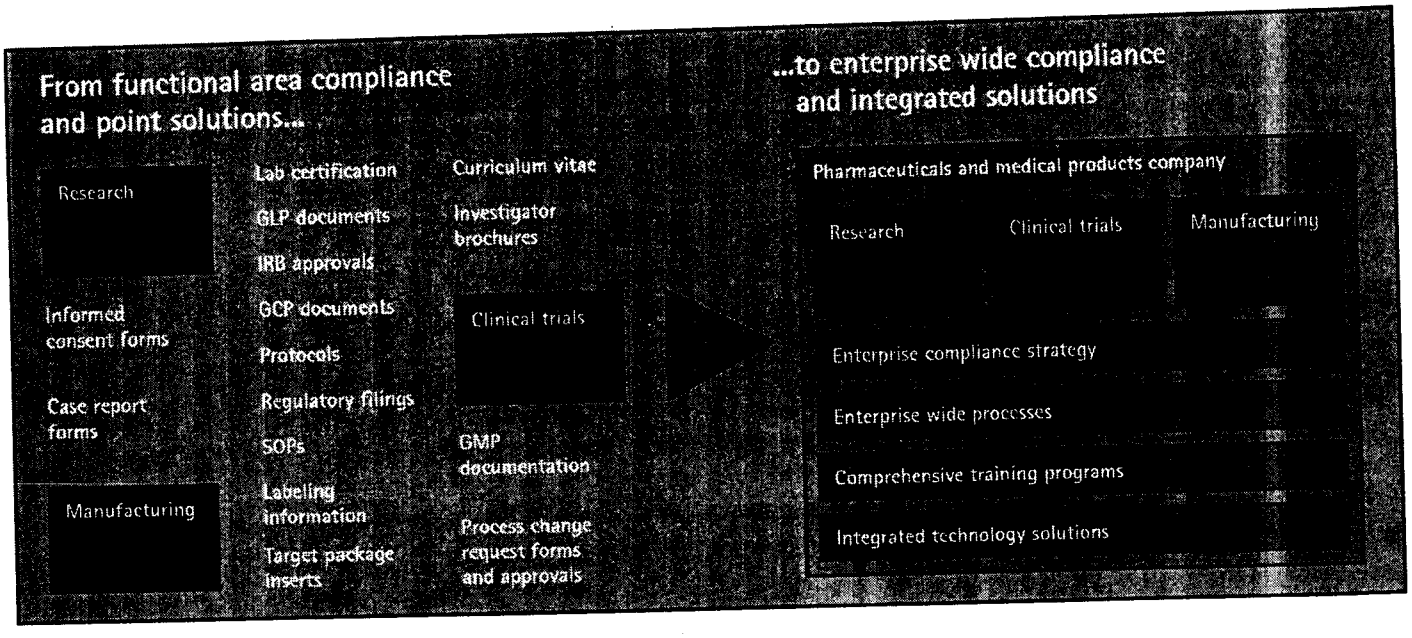
As pharmaceutical companies expand their participation in the digital economy, the compliance mandate, originating with the definition of information roles and authorities, can drive greater integrity, security, consistency and standardization. This, in turn, will improve speed and efficiencies across the organization and reduce risks associated with information exchanges with business partners.

Architect an enterprise-wide plan that includes people, processes and technology

Companies typically focus their Part 11 program on their information systems and do not include their people, processes and technology infrastructure. In addition, there are often several decentralized Part 11 efforts within an organization. These common practices unnecessarily drive up the cost of compliance and allow for gaps.

Part 11 compliance approaches should address people and processes as well as technology, taking a strategic IT perspective. Replacing current methods with an enterprise-wide approach to compliance that includes the procedural and technical aspects of the rule will create a more complete, less costly

Figure 04
Achieving enterprise wide compliance



Institute a corporate-wide interpretation of the regulation, create central policies, guidelines and training and manage the compliance/ remediation program centrally. This strategy leverages the skills of the appropriate people within an organization, eliminates redundancies and ensures complete coverage. An example of how to institutionalize this strategy follows.

Many organizations are creating a new functional area that incorporates Quality and IT responsibilities. Some specific responsibilities for this function would include:

- Attending public workshops and exploiting information sources to keep abreast of current regulations, interpretations, citations and issues
- Establishing and documenting interpretations, policies, guidelines, templates and procedures
- Providing training and advice/ guidance
- Supporting, reviewing and approving CSV and change control activities
- Acting as first point of contact for the FDA
- Being accountable for Part 11 compliance/remediation program

Design the technology architecture with Part 11 requirements in mind to leverage technology across applications and across the enterprise. This will simplify remediation efforts and lessen the long term maintenance and technology migration costs.

Some companies may choose to re-architect their infrastructure as part of their e-Commerce strategy. This should be undertaken in conjunction with their Part 11 compliance program. That way, companies can leverage their architecture design to enable Part 11 compliance for several systems. If architected appropriately, users can log on to a network once, taking care of authentication at this point of entry, and have access to many different systems, all of which

Address people and processes as well as computer systems when pursuing Part 11 compliance. FDA inspectors' knowledge is greatest in the area of people and processes, followed by systems (applications) with little knowledge/experience in infrastructure. It is important, therefore, not to ignore any component of your compliance and/or remediation strategy.

21 CFR Part 11 governs both electronic signatures and electronic records. Electronic signatures are not yet widely implemented. Companies that have moved in that direction have done so recently, and therefore, the technology is able to meet the requirements of 21 CFR Part 11. The main challenge with electronic signatures is the cultural challenge. Issues around not sharing passwords, logging off when leaving the workstation and the equivalence of electronic and handwritten signatures need to be addressed.

Open systems require additional controls beyond those identified for closed systems. The technology exists to digitize signatures and provide encryption; however, that is not where the challenges end. Many open systems require interaction with people outside the company walls (e.g., clinical investigators or suppliers). Issues associated with developing appropriate procedures, training and documentation for these individuals and ensuring they use the system in a compliant manner are as important as meeting the technology requirements of Part 11.

Be pragmatic in staging the implementation

Achieving Part 11 compliance will require an ongoing program and resources similar to the effort behind GxP compliance.

Companies that have not achieved Part 11 compliance already should, at a minimum, perform the following to clearly indicate progress with their Part 11 program:

- **Generate an inventory of what falls within the scope of Part 11**
- **Identify gaps in current compliance (map to long-term vision)**
- **Document justification for continued use of non-compliant systems**
- **Create an implementation plan to reach compliance (encompassing procedures as well as technology implementations)**
- **Track progress against the implementation plan**

Keeping a focus on and getting ahead of the key areas of concern for the FDA reveal a proactive approach to Part 11 compliance. Companies should ensure appropriate controls are in place for security, data integrity, audit trails, and record retention. These areas represent the top issues identified in citations pertaining to non-compliance.

In addition, all systems that are developed or upgraded for Part 11 compliance must be validated. Without this "documented evidence", any effort to achieve compliance with this regulation has been for naught.

Some issues associated with Part 11 are more difficult to overcome than others. For example, electronic records – in particular, historical information and its retrieval – are one of the more complex challenges pharmaceutical and medical device companies face today. With technology changing at such an incredible pace, the "life" of electronic records far exceeds the life of any given system. Most new systems are not designed to inherit all the records from a legacy system; in addition, retention requirements are still the same as they were for paper records. Archiving has therefore become a very large issue.

While archiving is a seemingly daunting task, it is possible to identify strategies that both meet regulatory requirements and are pragmatic. The examples below illustrate some approaches to the archiving issues.

To prevent the archiving issue from becoming larger over time, minimize the number of applications that keep compliance related information. Also, minimize the physical distribution of electronic records, i.e., store centrally and provide distributed access.

Many systems have archiving capabilities; however, they require the application software to view the data. One solution to this archiving challenge is to archive data independent of the application needed to create and/or access the data. Instead, the data is stored in a "data warehouse" or "document repository" and a "front-end" is built to retrieve and view the data.

Summary

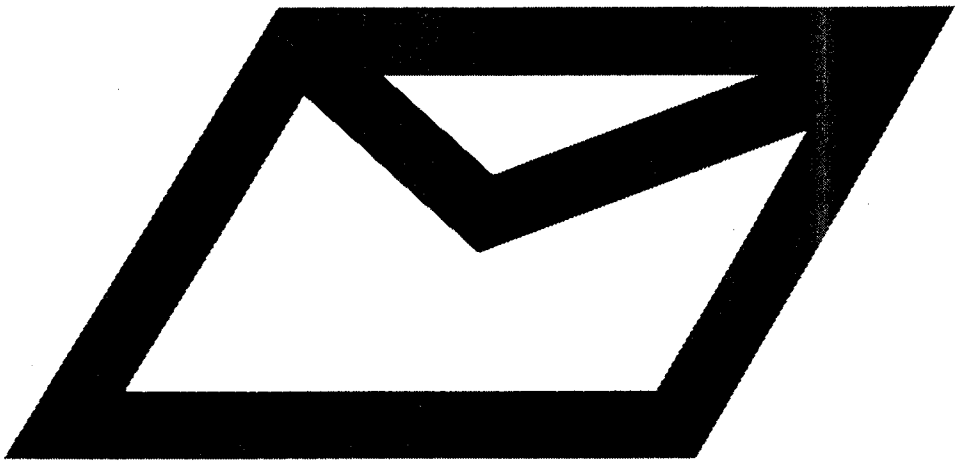
There are concerted actions companies can take to achieve business benefits while managing the cost and complexities associated with meeting regulatory requirements.

Industry has already spent a significant amount of time and money working towards Part 11 compliance. Yet, more work is required to remediate legacy systems and convert to electronic records and signatures.

Addressing regulatory compliance has typically been seen as a "cost of doing business". The time has come to view compliance in a different light. Part 11 initiatives should be aligned with enterprise-wide quality and technology programs to contain the remediation effort and reduce both regulatory and business risks. This will accelerate realizing the benefits from moving to a high quality, digitally-enabled business model.

There are four actions companies can take to both promote a value-adding electronic environment and ensure compliance.

- Incorporate Part 11 requirements as part of a corporate-wide quality program. This will both ensure overall regulatory compliance and reduce business and legal risks, by bringing regulatory compliance to the attention of the appropriate people.
- Manage the cost and complexity of regulatory compliance. Approaching Part 11 correctly will add incremental costs, but these costs can be contained with proper planning and implementation.
- Architect an enterprise-wide Part 11 plan when addressing compliance, including people, processes and infrastructure as well as information systems. Eliminate redundant efforts, leverage skilled resources and ensure complete regulatory compliance coverage.
- Be pragmatic when addressing Part 11 requirements. Focus on ensuring data integrity, security and other key issues. This focus will lead to good business decisions as well as achieve compliance.



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